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IN THE

Supreme Court of the United States

LABORATORY CORPORATION OF AMERICA HOLDINGS, dba LABCORP.

Petitioner,

v.

METABOLITE LABORATORIES, INC., *et al.*,

Respondents.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

AMICUS CURIAE BRIEF OF AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF RESPONDENT

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AMICUS CURIAE BRIEF OF THE AMERICAN INTELLECTUAL PROPERTY LAW ASSOCIATION IN SUPPORT OF RESPONDENT

The American Intellectual Property Law Association ("AIPLA") respectfully submits this Brief as *amicus curiae* in support of Metabolite Laboratories. AIPLA urges the Court to leave unchanged the current test described in *Diamond v. Diehr*, 450 U.S. 175 (1981), for evaluating patentable subject matter under 35 U.S.C. § 101. The *Diehr* test properly reflects Congress's intent that "anything under the sun made by man" is patentable subject matter.

STATEMENT OF INTEREST[1]

AIPLA has no interest in any party to this litigation or stake in the outcome of this case, other than its interest in seeking a correct and consistent interpretation of the law affecting intellectual property.

AIPLA is a voluntary bar association of more than 17,000 members who work with patents, trademarks, copyrights, trade secrets, and the legal issues that intellectual property presents. AIPLA's members include attorneys in private and corporate practice and in government service who secure, license, enforce, and defend against infringement of intellectual property rights.

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1. In accordance with Supreme Court Rule 37.6, AIPLA states that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than AIPLA or its counsel.

AIPLA sought consent to file this *amicus curiae* brief from the counsel of record for all parties, pursuant to Supreme Court Rule 37.3(a). Counsel for all parties have consented. Copies of the letters of consent have been filed concurrently with this Brief.

QUESTION PRESENTED

The Petitioner's question has the potential to implicate several aspects of patent law, most notably, issues arising under 35 U.S.C. § 112. In addition, the question raises alleged public policy concerns over limiting a physician's practice of medicine.

This Court elected to consider the following question: "whether a method patent setting forth an indefinite, undescribed, and non-enabling step directing a party simply to 'correlat[e]' test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result."

This question does not clearly articulate recognized patent law issues. However, the terminology used in the question presents the issue of whether Claim 13 of U.S. Patent No. 4,940,658 ("the '658 patent") satisfies the definiteness, written description, and enablement requirements of 35 U.S.C. § 112. Claim 13 was found by the jury to meet these requirements, the trial court held substantial evidence existed to support the jury's verdict,[2] and the Federal Circuit affirmed.[3]

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2. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, No. 99-Z-870 (D. Colo. Nov. 19, 2001).

3. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1372 (Fed. Cir. 2004).

The second part of the Petitioner's Question, improperly focuses on one step of a multistep process claim and invokes the now discredited–"mental steps" and "human steps" doctrines.[4]

The section 112 patentability issues and public policy concerns presented in the Petitioner's Question and initial Petition for Writ of Certiorari do not appear to be the issues under consideration by this Court. Instead, this Court's request for the views of the Solicitor General suggests an intention to consider whether Claim 13 satisfies a different section of the Patent Act, 35 U.S.C. § 101, defining statutory subject matter.[5] Specifically, the Court appears willing to consider whether Claim 13 falls within one of the judicially created exceptions to patentable subject matter: laws of nature, natural phenomena, and abstract ideas, even though this issue was not raised or argued at trial or on appeal to the Federal Circuit.

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4. *See In re Musgrave*, 431 F.2d 882, 893 (C.C.P.A. 1970) (rejecting the mental steps doctrine); *Alco Standard Corp. v. Tennessee Valley Authority*, 808 F.2d 1490, 1496 (Fed. Cir. 1987) (rejecting the human steps doctrine). *See also Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, 1300 Off. Gaz. Pat. Office 142 (Nov. 22, 2005) (discussing the rejection of the mental steps and human steps doctrines).

5. On February 28, 2005, this Court requested briefing by the Solicitor General on the following question: "Is the patent invalid because one cannot patent 'laws of nature, natural phenomena, and abstract ideas?'" Brief for the United States as Amicus Curiae at 4, *Lab. Corp. of Am. v. Metabolite Labs., Inc.*, 126 S. Ct. 601 (2005) (No. 04-607) [hereinafter "Brief for the United States"].

The question for review implied by the Court's question to the Solicitor General is whether a practical application of a natural phenomenon is patentable subject matter under the broad standard of 35 U.S.C. § 101.

SUMMARY OF ARGUMENT

Petitioner never alleged at trial that Claim 13 failed to satisfy the requirements of 35 U.S.C. § 101. In addition, the issue was never presented to the Federal Circuit for review and should be considered waived. The record lacks any evidence or analysis of whether Claim 13, as a whole, meets the requirements of section 101. The record is underdeveloped largely because the Parties did not dispute any aspect of the "assaying" step and focused solely on the "correlating" step.[6] Because this Court generally refrains from addressing issues that were not raised or considered below, it should decline to consider, in the first instance, whether Claim 13 recites patentable subject matter.

If the Court nonetheless considers the issue, the case should be remanded to the trial court for an analysis of appropriate facts on the record. As this Court has recognized, Congress broadly defined the scope of patentable subject matter under section 101 to encompass "anything under the sun made by man."[7] The language of section 101 places few limits on the types of invention eligible for patent protection. The broad language of the statute reflects Congress's judgment regarding how best to fulfill its Constitutional

6. *Metabolite*, 370 F.3d at 1364 & n.1.

7. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).

mandate to promote the advancement of the useful arts and sciences.

Consistent with the broad language of section 101, this Court has recognized only a few exceptions to patentable subject matter. These exceptions have been narrowly construed to preclude only those patent claims directed to laws of nature, natural phenomena, or abstract ideas, in isolation.[8] Although laws of nature, natural phenomena, and abstract ideas cannot be patented in isolation, the application of a law of nature, natural phenomena, or abstract idea to a useful process or product may be patentable under section 101.[9] It is irrelevant whether a portion of a patent claim, viewed in isolation, would or would not satisfy section 101. Rather, if the claim as a whole recites patentable subject matter, it satisfies the liberal standard of section 101.[10]

Proper analysis of Claim 13 evaluates if the claim in its entirety, including the preamble and all method steps, is directed to a law of nature, a natural phenomenon, or an abstract idea in isolation, or if the claim instead is directed to the application of a law of nature to a practical purpose. Claim 13 recites a method for diagnosing a deficiency in cobalamin or folate including a preamble calling out a

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8. *Diamond v. Diehr*, 450 U.S. 175, 184 (1981).

9. *See* Edward C. Walterscheid, *Divergent Evolution of the Patent Power and the Copyright Power*, 9 Marq. Intell. Prop. L. Rev. 307, 348 (2005) ("If [natural phenomena, laws of nature, or abstract ideas] are employed . . . as to produce a utilitarian result, the patentable 'discovery' resides in the embodiment or process that makes use of them to produce the useful result . . . .").

10. *Diehr*, 450 U.S. at 192.

diagnostic purpose and steps that accomplish that purpose. On remand, the trial court should consider whether the claim as a whole, including the preamble and the method steps of "assaying" and "correlating," meets the requirements set out in *Diamond v. Diehr*, where this Court construed and applied the constitutional mandate to promote the useful arts and sciences.

As a whole, does Claim 13 describe a useful application of the inventors' discovery that an elevated level of total homocysteine is an indicator of cobalamin or folate deficiency? If a factual basis is established to show that Claim 13 recites more than a mere law of nature in the abstract, the claim should pass the low threshold for patentable subject matter under section 101. Other provisions of the patent laws, including section 112 issues of definiteness, written description, and enablement, as well issues under sections 102 (novelty) and 103 (non-obviousness) can then be employed to test the patentability of the claim.

AIPLA urges the Court not to disturb the broad and accessible threshold of statutory subject matter that has fostered innovation and public disclosure over a wide variety of useful arts, and importantly, in new and emerging fields of technology, including the important area of diagnostic medicine involved in this case.

ARGUMENT

I. THIS CASE IS NOT THE APPROPRIATE VEHICLE FOR ADDRESSING THE SCOPE OF PATENTABLE SUBJECT MATTER UNDER SECTION 101.

This Court generally refrains from addressing issues that were not raised before, or considered by, the lower courts. *See* Sup. Ct. R. 14.1(a); *Adarand Constructors, Inc. v. Mineta*, 534 U.S. 103, 109 (2001); *Taylor v. Freeland & Kronz*, 503 U.S. 638, 646 (1992). As several *amici*, including the Office of the Solicitor General, have indicated, Petitioner never argued to the trial court or to the Federal Circuit that Claim 13 failed to satisfy section 101, and thus waived the issue.

Petitioner's section 101 invalidity claim was never presented to the jury at trial. The special verdict form presented to the jury recited the following for invalidity: lack of enablement, insufficient written description, indefiniteness, obviousness, and anticipation. Enablement, written description, and indefiniteness are all invalidity defenses arising under 35 U.S.C. § 112. Obviousness is a defense under section 103, and anticipation arises under section 102. None of Petitioner's invalidity defenses presented at trial involved section 101.

Consistent with its trial presentation, Petitioner's Brief to the Federal Circuit never mentioned section 101, nor did it contain any argument that Claim 13 failed to recite patentable subject matter. Rather, Petitioner simply made a single passing reference to this Court's decision in *Diehr*, in support of Petitioner's argument that the Federal Circuit should reverse the district court's claim construction.

The Federal Circuit was never presented with argument relating to the assaying step of the multistep claim. The parties rested the infringement analysis and issues of claim construction on the correlating step of Claim 13. In response, the Federal Circuit noted "[t]his Court, therefore, does not address the assaying step." *Metabolite*, 370 F.3d at 1364. Because the failure to meet the requirements of section 101 was never raised below, it is not surprising that the Federal Circuit's opinion did not address this issue.

This Court should not address, in the first instance, an issue that was never presented to the district court or to the Federal Circuit. This case is not of such exceptional importance that it warrants review on an issue neither presented, nor passed upon, below. *Cf. Duignan v. United States*, 274 U.S. 195, 200 (1927). AIPLA submits the Court should, at most, remand the case for development of the record on Petitioner's section 101 invalidity claim so that the trial court and/or the Federal Circuit can meaningfully review the issue, *if it is to be* considered *by this Court*.

II. *DIAMOND v. DIEHR* CARRIES OUT THE INTENT OF CONGRESS TO BROADLY DEFINE THE SCOPE OF PATENTABLE SUBJECT MATTER

The United States Constitution authorizes Congress "[t]o promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." U.S. Const. art. I, § 8, cl. 8. In pursuit of its Constitutional mandate to promote the progress of the useful arts, Congress broadly defined the scope of patentable inventions in 35 U.S.C. § 101, which states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of

> matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of [Title 35 of the United States Code].[11]

This Court has interpreted the language of section 101 broadly: "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). Devoid of limiting language, section 101 readily accommodates the rapid pace of innovation and the assimilation of new technologies, including technologies never anticipated at the time section 101 was enacted. Since 1796, the broad and expansive terms of the Patent Act have embraced inventions in fields as diverse as mechanical, electrical, and chemical subject matter, electronics, plants, animals, biotechnology, nanotechnology, computers, and software.

As this Court recognizes, the legislative history of the 1952 Patent Act shows that Congress intended inventors to be able to patent "anything under the sun that is made by man." *Chakrabarty*, 447 U.S. at 308-09 (quoting S. Rep. No. 82-1979, at 5 (1952); H.R. Rep. No. 82-1923, at 6 (1952)).

One strength of the Patent Act has been its lack of specific exclusionary limitations; permitting broad discretion in judicial interpretation and leaving the door open for as yet uncontemplated innovations and technologies. *See, e.g.*, Robert Greene Sterne & Lawrence B. Bugaisky, *The Expansion of Statutory Subject Matter Under the 1952 Patent*

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11. 35 U.S.C. § 101 (2000).

Act, 37 Akron L. Rev. 217, 225 (2004) ("Based on [the] history, there appears to be no compelling reason why future patentable subject matter in any technology area cannot be addressed under the current statutory provision."). Limiting access to the U.S. patent system by excluding technological advances such as the one at issue in this case, would stifle disclosure of inventions, limit research and development, and negatively impact innovations, particularly in emerging technologies.

Congress intentionally set the threshold for patentable subject matter under section 101 to be low. Recognizing this intent, the Court has defined exceptions narrowly so as to allow for a broad expanse of patentable subject matter. As the first hurdle to patentability, a broad scope of eligible subject matter permits easy entry for new and emerging types of subject matter. The public need not be concerned about this low threshold, however, as proof of patentability requires more than merely satisfying the subject matter requirements of section 101. The public domain is well protected by other, more stringent, criteria for patentability under Title 35, including novelty, nonobviousness, and sufficient disclosure. The doctrine of inherent anticipation prevents a patent claim from reciting solely a preexisting phenomenon, known or unknown, such as a principle of nature.

This Court's decision in *Diamond v. Diehr* presents a well-accepted and useful test for analyzing patentable subject matter under section 101. Although laws of nature, natural phenomena, and abstract ideas are, *in isolation*, unpatentable, this Court distinguished unpatentable abstract ideas from the practical and therefore patentable *application* of such discoveries. "It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure

or process may well be deserving of patent protection." *Diehr*, 450 U.S. at 187 (emphasis added); *see also Parker v. Flook*, 437 U.S. 584, 590 (1978) ("[I]t is equally clear that a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm."); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

In *Diehr*, this Court held that a claim that incorporated a mathematical equation constituted patentable subject matter because the claim, as a whole, defined a rubber molding process and not just an equation. *Diehr*, 450 U.S. at 192–93. Distinguishing *Parker v. Flook* as merely reciting a mathematical formula, the Court stated: "In contrast [to *Flook*], the respondents here do not seek to patent a mathematical formula. Instead, they seek patent protection for a process of curing synthetic rubber." *Diehr*, 450 U.S. at 187.

The mathematical formula at issue in *Diehr* was well known, as were the process steps of installing rubber in a press, closing the mold, and determining the temperature of the mold. Additional steps included "constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." Citing *Parker v. Flook*, the Court noted that "insignificant post-solution activity will not transform an unpatentable principle into a patentable process." *Id.* at 193. This was not the case for the *Diehr* claims, which applied the formula to a useful process:

> On the other hand, when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function

> which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of §101.

Id.

Flook was further distinguished in *Diehr* because the patent application in *Flook* lacked sufficient details of use outside the mathematical formula:

> We were careful to note in *Flook* that the patent application did not purport to explain how the variables used in the formula were to be selected, nor did the application contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit. All the application provided was a 'formula for computing an updated alarm limit.'

Id. at 187 (citations omitted).

The *Diehr* Court explained that although laws of nature, natural phenomena, and abstract ideas are not patentable in isolation, if the claim as a whole recites an application of a mathematical formula to a new and useful process, section 101 is satisfied. *Id.* By the same token, the *Diehr* Court said that the unpatentability of a mathematical formula cannot be circumvented by limiting the use of the formula to a particular technological environment or by insignificant post-solution activity. "To hold otherwise would allow a competent draftsman to evade the recognized limitations on the type of subject matter eligible for patent prosecution." *Id.*

Applying the *Diehr* test for patentable subject matter under section 101, a first inquiry asks: does the claim include a mathematical formula, scientific principle, or phenomenon of nature? If so, does the claim, as a whole, apply or implement the mathematical formula, scientific principle, or phenomenon of nature in a useful process or product? If the answer is yes, the claim satisfies section 101.[12]

The *Diehr* test as developed by the Federal Circuit provides ample opportunity to determine if the application of a claimed invention would "wholly preempt" a natural principle. The scope of a patent claim is determined by considering not only the claim terms themselves, but also the meaning to be given those terms in light of the patent specification and the prosecution history, and in the eyes of a person of skill in the art. Moreover, a patent's preamble language (in this case, "[a] method for detecting a deficiency of cobalamin or folate in warm-blooded animals") may also provide definition of a useful purpose that reflects an accepted category of patentable subject matter within the terms of section 101.

The Federal Circuit has followed this Court's *Diehr* decision in analyzing patentable subject matter under section 101. *State Street Bank & Trust Co. v. Signature Fin. Group, Inc.*, 149 F.3d 1368, 1373-74 (Fed. Cir. 1998); *In re Alappat*, 33 F.3d 1526, 1544 (Fed. Cir. 1994); *Arrhythmia Res. Tech., Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1057 (Fed. Cir. 1992) ("[C]laims to a specific process or apparatus that is

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12. In *Diehr*, the Court also noted that a claim may be directed to patentable subject matter regardless of whether it would satisfy the novelty requirement of section 102, or the nonobviousness requirement of section 103. *Diehr*, 450 U.S. at 189-91.

implemented in accordance with a mathematical algorithm will generally satisfy section 101.").[13]

The Federal Circuit defined the threshold inquiry for any section 101 analysis as whether the invention as a whole is directed to patentable subject matter. *State Street Bank*, 149 F.3d at 1374. The focus of the inquiry is on the essential characteristics of the subject matter as a whole, namely its practical utility. *Id.* In *State Street Bank*, a determination that an algorithm in a patent claim was practically applied as a step in the method claim was sufficient for the claim to meet the requirements of section 101.

Where *State Street Bank* examined the patentable subject matter criteria for a machine that transforms data, the Federal Circuit thereafter applied the same criteria to process patent claims in *AT&T v. Excel Communications, Inc.*, 175 F.3d 1352 (Fed. Cir. 1999). Although *Diehr* held section 101 could be satisfied by a claimed invention that "transforms" an article to a different state, the Federal Circuit in *AT&T* explained that physical transformation is not an exclusive requirement, but rather an example of one way that a mathematical algorithm in a claimed process can be limited to a practical application, namely by producing a useful, concrete, tangible result. *Id.*

A process can produce a useful, concrete, tangible result, even when one of the steps could be carried out mentally. The Federal Circuit (and its predecessor court) have expressly rejected the "mental steps" and "human steps" doctrines, with

13. In *Arrhythmia*, Judge Rader noted that this Court's decision in *Diehr* "cut the Gordian knot" of confusing precedent that unnecessarily restricted the scope of patentable subject matter under section 101. *Arrhythmia*, 958 F.2d at 1061 (Rader, J., concurring).

respect to patentable subject matter. The Court of Customs and Patent Appeals noted that the fact that some process steps were carried out in the human mind did not render a process non-statutory subject matter. *In re Musgrave*, 431 F.2d 882, 893 (C.C.P.A. 1970). Similarly, in *Alco Standard Corp. v. Tennessee Valley Authority*, the Federal Circuit specifically rejected the notion that merely because a human can carry out some or all the steps of a process, the process is unpatentable. 808 F.2d 1490, 1496 (Fed. Cir. 1987). Rather, the practical application test of *State Street* should be applied, in accordance with current law. In sum, the inquiry for purposes of determining statutory subject matter is whether the claimed invention produces a useful, concrete, and tangible result. *Alco Standard*, 808 F.2d at 1496.

The precedents of this Court and the Federal Circuit on patentable subject matter are also reflected in the most recent Guidelines on patentable subject matter published by the United States Patent & Trademark Office. *Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility*, 1300 Off. Gaz. Pat. Office 142 (Nov. 22, 2005). The Guidelines note that a claim contains patentable subject matter if, when taken as a whole, it accomplishes a practical application. The practical application requirement is met if the claimed invention produces a "useful, concrete, and tangible result." *Id.* (citing *State Street Bank*, 149 F.3d at 1375). Although these Guidelines are not controlling, they demonstrate that the Patent Office also follows this Court's *Diehr* analysis when evaluating patentable subject matter under section 101.

In sum, where a claim includes a law of nature, natural phenomenon, or abstract idea (for example, a mathematical algorithm), an accepted analysis for determining the existence

of patentable subject matter under section 101 was announced by this Court in *Diehr*. The *Diehr* test, as applied by the Federal Circuit and utilized by the U.S. Patent Office, focuses on whether the claimed invention as a whole is directed to a practical application of a law of nature, natural phenomenon, or abstract idea to a process or apparatus in a way that produces a useful, concrete, and tangible result. This Court should reaffirm this test for patentable subject matter under section 101.

III. ANALYSIS OF CLAIM 13 FOR PATENTABLE SUBJECT MATTER UNDER SECTION 101 SHOULD APPLY THE *DIEHR* TEST.

Neither the district court nor the Federal Circuit addressed whether Claim 13 recited patentable subject matter. As discussed above, reconsideration of the important issue of patentable subject matter eligibility in a case where the record is not factually developed for the issue does not bode well for the many types of patent claims that might be affected by any such decision.

The Solicitor General and other *amici* suggest that this case be remanded for factual findings consistent with the analysis of patentable subject matter under section 101. An analysis of Claim 13 under section 101 should apply this Court's *Diehr* analysis, on factual evidence developed at trial. Evaluation of patentability under section 101 requires review of the claim as a whole, including the preamble and both method steps, and not merely the *assaying* step or the *correlating* step in isolation.[14]

14. *See Diehr*, 450 U.S. at 192; *State Street Bank*, 149 F.3d at 1375 ("It is irrelevant that a claim may contain, as part of a whole, subject matter which would not be patentable by itself.").

Following the *Diehr* test, a first inquiry might be whether the claimed invention includes a law of nature, natural phenomenon, or abstract idea. Assuming such an exception is found, the claim would then be reviewed as a whole to determine if more than a law of nature, a natural phenomenon, or an abstract idea, is recited. In other words, the proper inquiry for an analysis under section 101 is: Does the claim apply a law of nature, natural phenomenon, or abstract idea to an otherwise acceptable category of patentable subject matter, in a way that produces a useful, concrete, and tangible result?

Claim 13 recites:

> A method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of:
>
> > *assaying* a body fluid for an elevated level of total homocysteine; and
> >
> > *correlating* an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.

The preamble of Claim 13 recites that the claim is directed to a diagnostic method for detecting a deficiency of cobalamin or folate in warm-blooded animals. The method steps that follow the preamble recite the actions taken to accomplish the recited diagnostic method: *assaying* a body fluid to determine the amount of total homocysteine in the sample to determine if the amount is elevated; and *correlating* an elevated amount with a diagnosis of cobalamin or folate deficiency.

The '658 patent specification is generally directed to the accurate and early diagnosis of cobalamin and folate deficiencies that can lead to life-threatening disorders. The patent describes prior unsuccessful attempts to find a biological indicator for a deficiency of cobalamin or folate. None of the prior methods measured total homocysteine levels. Recognizing that elevated levels of total homocysteine can be correlated with both cobalamin and folic acid deficiencies, the patentee created the useful diagnostic method that is reflected in Claim 13.[15]

Like the patent claim at issue in *Diehr*, once the claim terms are fully construed and the section 101 issue is considered by the trial court, Claim 13 may be interpreted to include one of the judicially noted exceptions to patentable subject matter: a law of nature, natural phenomenon, or abstract idea (e.g., mathematical algorithm). The claim at issue in *Diehr* included a known mathematical formula that was applied in a process for molding rubber. Claim 13 at issue in this case does not recite a mathematical formula, but in one method step recites "correlating an elevated level of total homocysteine" in a body fluid with a deficiency of cobalamin or folate.

If the newly discovered relationship between total homocysteine and the recited vitamin deficiency is a "law of nature" or "natural phenomenon," the Court should then consider if the law of nature is applied to a practical result, as is proper, or if it is merely claimed in the abstract, which is not proper.

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15. The Federal Circuit noted that no additional confirmatory steps were necessary, and the correlation between total homocysteine levels and vitamin deficiency was novel. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1361-62 (Fed. Cir. 2004).

The Petitioner dissects Claim 13 into its pieces, choosing to ignore the "assaying" step as lacking novelty, and treating the balance of the claim as non-statutory. Such dissection of the claim is an improper analysis, as the majority in *Diehr* found:

> In order for the dissent to reach its conclusion it is necessary for it to read out of respondents' patent application all the steps in the claimed process which it determined were not novel or "inventive." That is not the purpose of the §101 inquiry and conflicts with the proposition recited above that a claimed invention may be entitled to patent protection even though some or all of its elements are not "novel."

Id. at 194.

In *Diehr*, this Court approached the analysis of the patentable subject matter by comparing the type of subject matter recited in the claims with the statutory categories: "[W]e think that a physical and chemical process for molding precision synthetic rubber products falls within the §101 categories of possibly patentable subject matter." *Id.* at 185. Here the claim is directed to a diagnostic method for detecting a vitamin deficiency.

The claims in *Diehr* involved the "transformation of an article, raw, uncured synthetic rubber, into a different state or thing." The method steps detailed this transformation from loading the mold with the raw material to opening the press at the end of the cure period. "Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws." *Id.* However, as

indicated in *State Street Bank*, if a process converts information into a useful, tangible, and concrete result, a statutory process is also created.

As in *Diehr*, analysis of Claim 13 should consider if the claim as a whole contains the type of subject matter that has been eligible to receive the protection of the U.S. patent laws. Claim 13 recites a diagnostic method. The preamble recites the deficiency to be diagnosed, and the method steps describe how the diagnosis is to be accomplished. The format of the claim follows a standard pattern of diagnostic method claims having the diagnostic purpose in the preamble, with steps reciting the analysis of a disease marker and the use of the results of the analysis to determine the diagnosis of disease.

The Court in *Diehr* determined the claim at issue was not directed solely to claiming a mathematical formula, but rather the claimed process employed a well-known mathematical equation. The patent claims did not seek to preempt the use of that equation, but rather sought to "foreclose from others the use of that equation in conjunction with all the other steps in their claimed process." *Id.* at 188.

Similarly, analysis of Claim 13 should examine if the claims as a whole preempt the use of any "law of nature." The Solicitor General's *amicus* brief suggests that Claim 13 *may* run afoul of the rule against claiming every "substantial practical application" of a law of nature, such that the practical effect would be the grant of a monopoly on the law of nature itself.[16] *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972).

16. The Solicitor General acknowledges that the record is not fully developed, and thus cannot support a review of the validity of Claim 13 under section 101. *See* Brief for the United States at 17.

Claim 13 recites a method that employs the discovered relationship between a measured amount of total homocysteine in a sample and cobalamin or folate deficiency for purposes of a specific diagnosis. As the Solicitor General acknowledges, it is not clear if the factual record might be developed to expose other potential uses of the discovered relationship outside the claimed diagnosis. In any event, the scope of Claim 13 may not extend beyond the specific diagnostic method recited in the claim.

Applying the *Diehr* test of patentability to Claim 13, a trial court would first consider if the claim recites a basic scientific principle or phenomenon of nature. If so, the court, considering the subject matter of the claim as a whole, including the diagnostic purpose recited in the preamble, and the assaying and correlating steps that carry out the diagnostic method, would determine if the law of nature is applied to a practical method protectable by the U.S. patent laws.

Many existing U.S. patent claims recite diagnostic methods that apply similar relationships between discovered biomarkers and the presence or absence of disease, and will be affected by any changes in the broad scope of patentable subject matter currently granted to medical diagnostic claims. For example, U.S. Patent No. 6,051,379 includes a claim directed to a well-known diagnostic method for detecting a predisposition to breast cancer by analyzing a patient sample for a mutated gene, BRCA-1, and correlating the presence of the mutation with a predisposition to breast cancer. A similar diagnostic method is claimed in U.S. Patent No. 5,599,677, where a measurement of the amount of free prostate-specific antigen (PSA) in a patient sample is correlated to the existence of prostate cancer.

The rapid discovery of biomarkers for disease, elucidation of genetic profiles for subgrouping diseases and patient populations, as well as prediction of an individual's response to therapy, is launching a new era of personalized medicine that will rely heavily on patent exclusivity for the financial stability and incentive to stimulate commercialization of new diagnostic tools.

Patented methods in other technological fields will also be affected by a decision in this case. Such claims could be directed to predicting weather conditions, such as earthquakes, hurricanes, or tornados. For example, U.S. Patent No. 5,546,800 includes a claim that recites the steps of measuring negative ion flow intensity in the air and correlating negative ion flow with imminent tornado formation.

As these examples show, many useful patented inventions apply a natural phenomenon or law of nature to a useful result. Congress intended that inventors of such processes would be able to seek protection via the patent system. Accordingly, AIPLA urges the Court to uphold the broad scope of patentable subject matter that Congress intended for 35 U.S.C. § 101, so that the U.S. patent system will continue to successfully promote the progress of the useful arts.

CONCLUSION

Because the instant case does not properly present the issue of whether Claim 13 contains patentable subject matter under 35 U.S.C. § 101, the Court should not address that issue. At most, the Court should remand for further development of the record and analysis of the 101 issue in the first instance by the trial court.

Should this Court choose to decide the section 101 issue on the limited record available, AIPLA urges the Court not to disturb the broad and accessible threshold of statutory subject matter that has fostered innovation and public disclosure over a wide variety of useful arts, and importantly, in new and emerging technology fields, including the important area of diagnostic medicine involved in this case.

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